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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 19

Application Number: 09/199,129
Filing Date: November 24, 1998
Appellant(s): BYRUM ET AL.

Lawrence M. Lavin, Jr.
David R. Marsh
June E. Cohan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 2, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment filed July 2, 2002, which canceled non-elected claims 2, 3 and 13-17 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 1 and 4-12 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

Claims 1 and 4-12 stand finally rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Claims 1 and 4-12 are drawn to a nucleic acid comprising a nucleic acid of SEQ ID NO: 1. SEQ ID NO: 1 is an EST isolated from soybean leaf tissue. Applicant asserts a general utility for this EST (as well as 5520 other EST isolated from the same source) as useful in the isolation of agronomically important genes, as well as generic uses such as antibody production, gene expression probe, marker, etc. The application does not disclose a utility specific for a nucleic acid comprising SEQ ID NO: 1 or a specific utility or activity for a protein or fragment encoded by a nucleic acid encoding SEQ ID NO: 1, nor does it disclose a specific utility for any full length gene which could be isolated using SEQ ID NO: 1.

The claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of the nucleic acids (and proteins encoded by said nucleic acids) are not specific and are generally applicable to any nucleic acid and/or protein. The specification states that the nucleic acid compounds may be useful as probes for assisting in the isolation of full-length cDNA's or genes which would be used

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to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages. Similarly, protein may be used for detection of expression, antibody production, Western blots, etc. These are non-specific uses that are applicable to nucleic acids and/or proteins in general and not particular or specific to the nucleic acids (and proteins encoded by said nucleic acids) being claimed.

Further, the claimed nucleic acid (and proteins encoded by said nucleic acids) are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have specific and substantial utilities. The research contemplated by applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the

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claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds (or proteins encoded by said nucleic acid compounds) such that another non-asserted utility would be well established for the compounds.

Because there is no specific utility for a nucleic acid comprising SEQ ID NO:1 (as discussed above), there is also no specific utility for a plant comprising a nucleic acid comprising SEQ ID NO:1, or its complement, nor is there any specific utility for methods of determining the level or pattern of a protein which has no specific utility using SEQ ID NO:1 or its complement.

Claim Rejections - 35 USC § 112

Claims 1 and 4-12 stand finally rejected under 35 U.S.C. § 112, first paragraph, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1 and 4-12 stand finally rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO: 1. SEQ ID NO: 1 meets the written description provisions of 35 USC 112, first paragraph. However, SEQ ID NO: 1 is a partial sequence, and the proper open reading frame has not been disclosed. Claims 1

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and 4-12 are directed to encompass full length gene sequences (i.e. gene sequences yet to be discovered) and cDNA's comprising SEQ ID NO: 1, sequences that hybridize to SEQ ID NO: 1, and so forth, as well as plants comprising said sequences and methods which utilize said sequences. None of these sequences meet the written description provision of 35 USC 112, first paragraph. For example, a cDNA **comprising** a partial sequence, as claimed, encompasses a wide variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region, however, the specification does not disclose an open reading frame for SEQ ID NO: 1 and, therefore, would not be representative of the breadth of the genus of cDNA's because no information regarding the coding capacity of any cDNA molecule would be disclosed. In the instant case, the specification discloses only a single common structural feature shared by the claimed genus, i.e. SEQ ID NO: 1, and this disclosed structural feature does not constitute a substantial portion of the claimed genus. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and

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reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in

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Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The one species specifically disclosed (i.e. SEQ ID NO: 1) is not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

(11) Response to Argument

Appellants' arguments drawn to the above rejections are noted, however, are not found persuasive for the following reasons.

Appellants argue that the claims satisfy the requirements under the 101 statutes because the claimed nucleic acids (and vectors comprising them) are useful in detecting the presence and level of mRNA in a sample; identifying polymorphisms; obtaining promoters and other flanking genetic elements to such molecules; determining the location of a corresponding DNA sequence on a genetic map; isolating related nucleic acid and protein molecules; conducting plant transformation or transfection and as probes for expression profiling, or as a tool for screening possible herbicide compounds.

These arguments have not been found persuasive because the specification has not disclosed any specific or substantial biologically significant activity for any nucleic acid comprising SEQ ID NO: 1, such that any of these utilities would be available to the

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skilled artisan in a substantial and real world context. Since no specific biological function has been ascribed to the claimed EST, and its corresponding putative protein, asserting that the nucleic acid can be used to determine the full length cDNA is non-specific, since no biological functionality can be ascribed to the full length cDNA. These general uses are non-specific in the absence of any biological function disclosed; the claimed sequences, nucleic acids comprising SEQ ID NO: 1, have only been disclosed as an EST, without any known biological function and without any open reading frame.

Appellants argue that the instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966), wherein the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is not a reward for the search, but compensation for its successful conclusion.

The utilities set forth by Appellants are considered to be non-substantial, as argued in the rejection under 35 U.S.C. 101, because the nucleic acids, by their presence or absence, or as probes, does not provide a real-world applicability to one skilled in the art. The nucleic acids, as disclosed, do not provide to the skilled artisan what the presence or the absence of the claimed nucleic acids would be useful for. For

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a nucleic acid to have a **substantial or real-world** utility, its presence or absence must relay to the artisan real-world applicable information, such as detection/predisposition of certain conditions (i.e., cancer markers) (emphasis added), or any other corresponding biological or disease related function of the protein. A statement indicating that the nucleic acids have substantial utility because it contains polymorphisms would not give an **immediately apparent**, or substantial utility, as the Court has expressed, because such apparent utility would not be found without conducting further research on each of the claimed polymorphisms (emphasis added).

Appellants' arguments drawn to the claimed nucleic acids being useful as probes are not found persuasive because any nucleic acid, by its inherent property, would hybridize to its complement. However, hybridization of such nucleic acid must relay to an ordinarily skilled artisan some real-world applicability. A nucleic acid could certainly be used as, for example, a probe for detecting a an mRNA associated with a particular condition, a primer for amplifying a region which would serve as an indication of something, determining the location of a corresponding DNA sequence on a physical or genetic map and, potentially, assist in determining the function of a gene, etc. However, the claimed nucleic acid lacks a substantial utility because the specification of the instant application fails to provide any teachings that indicate that the presence/absence of the claimed nucleic acids actually correlate to some disease, condition, or presence of harmful agents (i.e., bacteria), etc., or that the nucleic acid of SEQ ID NO: 1 codes for a protein with a particular biological activity with any practical characteristics. The instant application simply relies on the fact that probes have been patentable in the art

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and, since the claimed nucleic acids can be used as a probe, it must be patentable.

Such argument is not found persuasive because nucleic acid probes are not patented solely on their ability to hybridize to their complement. It is the information (a specific benefit, or an immediately applicable benefit) that is derived from the hybridization. In the instant case, Applicant has not provided any information or specific benefit which can be derived from the hybridization of the claimed nucleic acid and, therefore, would not provide any real word applicable benefit.

Applicants also argue that the probes could be used for expression profiling. It is true that a probe would be found to have an immediately apparent utility if by its over-expression or under-expression, an artisan could derive a useful information (such as diagnostic for conditions). However, Appellants fail to disclose such benefit. The artisan using the nucleic acids of the Appellants would not know why the artisan should use the claimed nucleic acids over any other polymorphic nucleic acids that are isolated from plants. Without further research, the skilled artisan would not have any reason, such as an immediately apparent benefit, to use the claimed polymorphic nucleic acid over other polymorphic nucleic acids isolated from plants.

It is noted that Appellants' attempt to attribute utility to the claimed polynucleotides through use of a microscope analogy. A microscope, by virtue of the invention, has a real world application in magnifying microscopic objects (that are known to exist) to which the human eyes are not capable of seeing. The real world application of a nucleic acid, however, does not lie in its inherent property of hybridizing to any template. The nucleic acid, by its hybridization or amplification, must infer useful

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information. It is that useful information (immediately useful benefit) which would give substantial utility to a nucleic acid. The instant application has failed to disclose such information to the artisan, because Appellant discloses no information that attributes any substantial and specific biological significance to the claimed nucleic acid fragment.

Appellants also state that the use of claimed nucleic acid molecules to detect the presence or absence of polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. This argument is not found persuasive because an artisan will be led to use a gas chromatograph for identifying, via separation, the contents of a particular elements in the gas, an immediately apparent benefit to the artisan. However, Appellants have not given any immediately apparent benefit (or substantial utility) for the artisan to use the claimed polymorphism over any other polymorphisms isolated from plants, because the polymorphism is not correlated with anything of specific biological significance other than identifying an EST. An immediately apparent benefit that would lead the skilled artisan to use a polymorphic nucleic acid would be, for example, cancer diagnostic (mutations in BRCA1 and BRCA2 which increases the likelihood of breast and ovarian cancer). Such disclosure would allow the artisan to realize the immediate benefit of using such polymorphisms over any other polymorphisms. The Appellants have failed to disclose such immediate benefit other than a laundry list of possible benefits that a nucleic acid could be used for.

It is noted that Appellants' attempt to attribute utility to the claimed polynucleotides through the use of a golf club analogy. In accordance with the

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Appellants' example, the golf club is useful and has utility in hitting a "golf ball," not any object. Its utility lies in hitting a golf ball. Similarly, the utility of a nucleic acid lies in what information it infers. Such information could be, "what does the presence/absence of the nucleic acid indicate," "what region does the nucleic acid amplify that gives significance," "what's the function of its encoded protein," etc. The instant application has failed to give such guidance to the skilled artisan.

Appellants' arguments drawn to the claimed nucleic acid being useful for screening an herbicide compound is not persuasive. Any expressed nucleic acid (ESTs) isolated from a particular source could be used in an expression study. However, the claimed nucleic acid, at best, would require of the skilled artisan **further research** (emphasis added) to find an immediate real-world applicable utility. If a nucleic acid was derived from a subtractive library (i.e., cancer), then the expression of a particular nucleic acid would give immediate utility to an ordinarily skilled artisan – to use it as a diagnostic tool. However, any nucleic acid would not give this immediate real-world utility to the artisan because none of the claimed nucleic acids are disclosed as having this immediate real-world applicability. The instant application fails to give any guidance to the artisan what immediate real-world applicable (or substantial) utility would arise when the claimed nucleic acid are expressed or differentially expressed.

Appellant argues that additional uses for the claimed nucleic acid molecules are as probes for other molecules, including a promoter of the gene corresponding to the claimed nucleic acid molecules, or as a source of primers, which can be used to initiate a chromosome walk. Appellant argues that this use is specific to the claimed nucleic

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acid molecules because the claimed nucleic acid molecules were isolated from leaves and, therefore, would be appropriate to provide a starting point for isolating a leaf specific promoter, which is not a property of a random nucleic acid molecule. Appellant argues that although nucleic acids may be used generally to identify and isolate related sequences, the claimed nucleic acids identify a unique subset of related sequences, specific to the nucleic acid molecule claimed and, therefore, is a specific use.

The claimed nucleic acids have not been associated with any specific or substantial gene, characteristic or protein and, therefore, it is unclear what use any related sequences, or what use an identified subset of related sequences would have. Appellant has not provided any factual support that an active promoter is associated with the claimed nucleic acid molecules. It is speculative that such a promoter exists, because multi-cistronic gene sets are known to exist in plants, and in such a situation no promoter may be connected to a gene, but, rather, a complex operon promoter may control these genes and may be exceedingly difficult to find and delineate. A myriad of promoters may be present in complex organisms, however, their utility is non-specific and non-substantial until further research determines the function of the associated gene or provides further information about the function of such a promoter.

Appellant argues that the commercial value of ESTs is proof of their real world value and of the benefits that they provide to the public. However, the instantly claimed ESTs have not been demonstrated to have any commercial value. The commercial value of other EST sequences may be supported by the completion of further research which has defined a specific and substantial use, or may be based on the potential for a

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substantial or specific use, which may or may not exist, and has not be provided by Appellant.

For the foregoing reasons, the utility rejection under 35 U.S.C. 101 is maintained.

The rejection of claims 1 and 4-12 under 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above one skilled in the art would not know how to use the claimed invention is maintained.

Appellants' arguments have been fully considered, but as set forth above, the utility of the claimed nucleic acids has not been not established and thus, the rejection is maintained.

In response to the rejection set forth under 35 U.S.C. 112, first paragraph, as lacking adequate written description, Appellants argue that Appellants have provided the nucleotide sequences required by the claims, e.g., SEQ ID NO: 1, which is the recitation of a common structural feature of the claimed genus of nucleic acids, and thus established possession of the claimed invention.

This argument is not found persuasive because the claims are directed to encompass a nucleic acid **hybridizing** to a second nucleic acid **having** (or comprising) a nucleic acid sequence SEQ ID NO: 1, and vector comprising them, etc. The issue at hand is whether or not the nucleic acid claimed (ie. sequence comprising SEQ ID NO: 1 or hybridizing to SEQ ID NO: 1) is properly described under the 112, first paragraph.

First of all, SEQ ID NO: 1 **does not** contain a complete open reading frame (emphasis added). Despite this fact, the claims recite nucleic acids that **comprise** SEQ ID NO: 1 and encompass methods which utilize nucleic acids which hybridize to a nucleic acid comprising SEQ ID NO: 1 or a complement of SEQ ID NO: 1, and methods which utilize a nucleic acid that comprises SEQ ID NO:1 or a complement of SEQ ID NO:1, which would include a full-length cDNA and possibly a gene (if the SEQ ID Number is from a single exon). Therefore, the claims encompass nucleic acid sequences that are not described and method that require nucleic acids that have not been described. The nucleic acid claimed, SEQ ID NO:, does not contain a full open reading frame, and the claims encompass a full-length cDNA sequence, as well as gene sequences that hybridize to SEQ ID NO:1. According to the Written Description guideline, example 7 (see Attached), such claims read on an a full-length cDNA and gene containing regions undescribed by the Appellants, rendering the claims improperly described under 112, first paragraph.

Appellants are advised that the rejection is being maintained in accordance with the PTO technology center guidelines.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

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October 3, 2002

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